I. AMENDMENTS TO THE CLAIMS

This listing of the claims will replace all prior versions and listings.

Listing of Claims:

Claims 1-28 canceled.

Claim 29 (previously presented) A method of preventing hemophilic bleeding in advance of a bleeding event, said method comprising:

a) aerosolizing a monomeric Factor IX (FIX), wherein the aerosolized monomeric FIX: i) has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm, ii) has a fine particle fraction percent less than 3.3 μm (FPF %<3.3 μm) of at least 50%, iii) is at least 90% monomeric, iv) wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%; and v) is a dry powder having less than 10% water (wt/wt), but does not have ethanol;

b) slowly maximally inhaling aerosolized monomeric FIX; and

c) allowing said monomeric FIX to deposit in the deep lung tissue such that said monomeric FIX is sequestered in said deep lung tissue to provide sufficient FIX to prevent bleeding for at least 100 hours after administration.

Claim 30 (cancelled).

Claim 31 (canceled).

Claim 32 (currently amended) The method of claim 29, wherein said FIX is prepared by

a) diafiltering concentrated FIX solution to a concentration of approximately 12 mg/ml;

b) spray drying the diafiltered solution at ~~between~~ 40 ~~and~~ or 60 psi and ~~between~~ 60°C ~~and~~ or 70°C at 5 ml/min and ~~approximately~~ 17.8 standard cubic feet per minute (scfm); and

c) transferring spray dried FIX to a sealed storage container at less than 5% relative humidity.

Claim 33 (previously presented) A prophylactic method of treating hemophilia, said method comprising

a) aerosolizing a monomeric Factor IX (FIX), wherein the aerosolized monomeric FIX: i) has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm, ii) has a fine particle fraction percent less than 3.3 μm (FPF %<3.3 μm) of at least 50%, iii) is at least 90% monomeric, iv) wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%; and v) is a dry powder having less than 10% water (wt/wt), but does not have ethanol;

b) slowly maximally inhaling aerosolized monomeric FIX;

c) allowing said monomeric FIX to deposit in the deep lung tissue, and

d) followed by exhalation, wherein said monomeric FIX is sequestered in said deep lung tissue to provide sufficient FIX to prevent bleeding for at least 100 hours after administration.

Claim 34 (canceled).

Claim 35 (canceled).

Claim 36 (currently amended) The method of claim 33, wherein said FIX is prepared by

a) diafiltering concentrated FIX solution to a concentration of approximately 12 mg/ml;

b) spray drying the diafiltered solution at ~~between~~ 40 ~~and~~ or 60 psi and ~~between~~ 60°C ~~and~~ or 70°C at 5 ml/min and ~~approximately~~ 17.8 standard cubic feet per minute (scfm); and

c) transferring spray dried FIX to a sealed storage container at less than 5% relative humidity.

Claim 37 (previously presented) A method of preventing hemophilic bleeding in advance of a hemophilic assault, said method comprising:

a) aerosolizing a Factor IX (FIX), wherein the aerosolized FIX: i) has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm, ii) has a fine particle fraction percent less than 3.3 μm (FPF %<3.3 μm) of at least 50%, iii) is at least 90% monomeric, iv) wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%; and v) is a dry powder having less than 10% water (wt/wt);

b) inhaling the aerosolized FIX at least once per week and allowing the aerosolized FIX to deposit in the lung; and

c) followed by exhalation wherein said monomeric FIX is sequestered in said lung tissue to provide sufficient FIX to prevent bleeding for at least 100 hours after administration.

Claim 38 (canceled).

Claim 39 (canceled).

Claim 40 (previously presented) A prophylactic method of treating hemophilic bleeding, said method comprising:

a) aerosolizing a Factor IX (FIX), wherein the aerosolized FIX: i) has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm, ii) has a fine particle fraction percent less than 3.3 μm (FPF %<3.3 μm) of at least 50%, iii) is at least 90% monomeric, iv) wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%; and v) is a dry powder having less than 10% water (wt/wt);

b) slowly maximally inhaling aerosolized monomeric FIX; and

c) allowing said monomeric FIX to deposit in the lung such that said monomeric FIX is sequestered in said lung to provide sufficient FIX to prevent bleeding for at least 100 hours after administration.

Claims 41 – 52 (cancelled).